EXHIBIT 31

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL	) MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	) CIVIL ACTION NO.
PRICE LITIGATION	) 01-CV-12257-PBS

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THIS DOCUMENT RELATES TO:	)
The City of New York v. Abbott Labs., et al.	)
(S.D.N.Y. No. 04-CV-06054)	)
County of Suffolk v. Abbott Labs., et al.	)
(E.D.N.Y. No. 03-CV-229)	)
County of Westchester v. Abbott Labs., et al.	)
(S.D.N.Y. No. 03-CV-6178)	)
County of Rockland v. Abbott Labs., et al.	)
(S.D.N.Y. No. 03-CV-7055)	)
[Caption continues on Next Page]	)

Washington, D.C.

Monday, May 20, 2008

9:30 a.m.

VIDEOTAPED DEPOSITION OF GAIL SEXTON

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topics of conversation. And there were probably very few, but I'm sure there were times when I did speak with her about the program in general.
Q. But is it fair to say you wouldn't be knowledgeable about the process, for example, that Ms. Gaston used to establish FULs during the period of time where she was the lead?
MR. FAUCI: Objection, form.
A. No.
Q. Or the information on which she chose to rely while she was the lead for setting FULs?
MR. FAUCI: Objection, form.
A. No.
Q. Or the objectives that she sought to achieve when she was setting FULs? You wouldn't have any knowledge of that?
MR. FAUCI: Objection, form.
A. No, I would not.
Q. Just so we set out a clear time period here, it's my understanding that CMS hasn't updated its FUL list since December of 2006. Is that consistent with your understanding?

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A. That's correct.
Q. And the reason that CMS hasn't updated a FUL list since 2006 is because of the advent of the DRA?
A. Correct.
Q. And what do you understand me to mean by the DRA, just so the term is clear on the record?
A. The DRA is the Deficit Reduction Act of 2005. And there were several provisions passed in the Deficit Reduction Act that changed the federal upper limit program, changed the definition of a multiple source drug, changed the methodology by which the federal upper limit is calculated.
Q. What methodology for calculating the federal upper limit was proposed in the DRA?
MR. FAUCI: Objection, form.
A. The DRA establishes the federal upper limit to be 250 percent of the lowest average manufacturer price for the lowest therapeutically and pharmaceutically equivalent average

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manufacturer price within a drug group.
Q. Sounds like you've stated that before. What is an average manufacturer's price?
MR. FAUCI: Objection, form.
A. The average manufacturer price, my understanding of that is the price that the wholesaler obtains the drug from the manufacturer.
Q. Is it otherwise known as AMP?
A. Yes.
Q. And there's a statutory definition of AMP or average manufacturer's price, correct?
MR. FAUCI: Objection, form.
A. In our drug rebate rule, our major rule that we published in July of 2007, even though I did not have the lead on the AMP definition or the entities that were included or excluded from AMP, that is discussed in that regulation.
Q. But there's a definition of AMP that exists to your knowledge?
MR. FAUCI: Objection, form.
A. I believe that there is in the drug

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rebate agreement.
Q. Okay. And in your role as the program lead on FULs you say that the FUL list hasn't been updated since December of 2006, correct?
A. Correct.
Q. So it fair then to assume that the DRA methodology, the 250 percent of AMP, hasn't been implemented as of today?
MR. FAUCI: Objection, form.
A. Correct. We have not published any federal upper limit prices under that methodology.
Q. So then is it fair to assume that the period of time for which you've reviewed and updated the FUL list really is December of 2004 to December of 2006, so it's the 2005-2006 period?
MR. FAUCI: Objection, form.
A. At some point after October 31st 2004 until December 2006 as far as the updates on the FUL.
Q. I'm from here on out going to try and

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concentrate my questions on that, that period of October 31, 2005 to December of 2006. So if you would just kind of keep that in mind in your answers things will go smoothly.
MS. OBEREMBT: John, did you mean to say October of 2004?
MR. BUEKER: I did. What did I say?
MS. OBEREMBT: 2005.
MR. BUEKER: Oh. Sorry.
BY MR. BUEKER:
Q. Just so the record is clear, I'm going to try and confine my questions to October 2004 to December 2006. If you'd keep that in mind it would be appreciated.
A. Sure.
MR. BUEKER: I ask the court reporter to mark at this time two exhibits, Sexton Exhibit 4 for identification is a one page document that bears the Bates number HHD 175-1456.
(Exhibit Sexton 004 was marked for identification.)
MR. BUEKER: And at the same time,

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because I think they're related, let's mark HHD 175-1455 as Exhibit 5 for identification, please.
(Exhibit Sexton 005 was marked for identification.)
THE WITNESS: (Reading.)
BY MR. BUEKER:
Q. Ms. Gaston, please let me know when you've had a chance to look at Exhibit 4 and Exhibit 5.
A. I'm Ms. Sexton.
MR. FLESSNER: You said Gaston.
MR. BUEKER: Gosh I'm having a rough morning.
MS. OBEREMBT: Do you want some coffee?
MR. BUEKER: I do.
THE WITNESS: Okay.
BY MR. BUEKER:
Q. Just for the record, would you identify and explain what Exhibit 4 is?
A. Exhibit 4, this would be a printout sheet from the federal upper limit software system. This is what the sheets look like when

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they're printed off.
Q. Okay. And what is Exhibit 5?
A. Exhibit 5, this is my handwriting, and this is -- appears to be the information from the federal upper limit system. However, I do not know why I would have -- usually if I was obtaining information myself through one of the compendia I would handwrite in information. So I don't know if I put this together before the information was downloaded into the compendia or -- I don't know the exact reason why. But I wrote this, I guess.
Q. I just will note for the record that this is not a drug that's at issue in the New York Counties. I just thought this might be an easy way to illustrate kind of your process. By why don't you just walk us through what you typically do in terms of setting a federal upper limit.
A. Okay. When it's determined that a drug is available as a multiple source drug and we have several sources to use for that, the FDA --

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there's an FDA website. We use a resource from the Food and Drug Law Institute. The different sources that we would use to identify when a drug is available as a multiple source drug; then we would look at the drug to determine whether it met the criteria under the federal regulations statute whereby we would have two As in the FDA's Orange Book.
If there was a B-rated drug or a formulation other than an A-rated drug in the FDA Orange Book then we would have needed three As as our first criteria. And then we would have to have three suppliers from our compendia. Generally we would get that information from one of the three compendia that we use.
Q. And those are the criteria you'd apply in establishing a federal upper limit?
MR. FAUCI: Objection, form.
A. Yes.
Q. Those are the criteria that CMS would apply in establishing a federal upper limit?
A. Yes.

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MR. FAUCI: Objection, form.
A. It appears that it was a supply issue.
Q. And that decision was made in part based on feedback that Deirdra Duzor, your superior, received from the National Association of Chain Drug Stores?
A. And feedback that I received as well. And like I said, this was a gray area. And that's why I took it to Deirdra Duzor to make the decision.
Q. But a judgment was made to remove the FUL?
A. Correct.
Q. Apart from through the PTAG and through the National Association of Chain Drug Stores, how else did you receive feedback on issues like availability in the marketplace?
A. It was from pharmacy providers or states. I would receive e-mails about -- and other drugs as well on supply issues or cost issues.
Q. Was there a formalized process

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established or how did you receive that feedback?
A. No. There was no formalized process established. But the providers would contact me generally by e-mail, sometimes by written letter, that a drug was not available or a drug was not available at cost or within the federal upper limit reimbursement amount.
Q. How frequently did you get that kind of feedback from providers in the marketplace?
A. I would say fairly often. Not so much just about this drug, but all drugs.
Q. And what if anything did you do in reaction to the feedback you were receiving about a market availability?
A. I would look at the availability in the compendia or I may call suppliers or check -- you know, verify price availability per the criteria.
Q. And can you think of instances in which you made a decision to change the federal upper limit based on the feedback you were receiving?
MR. FAUCI: Objection, form.
A. I can't remember individual drugs or

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ingredient, route, strength, dose, product groups. But yes, changes were made to the federal upper limit based on a pharmacy provider giving us feedback. Not because they gave us feedback, but it would be the impetus for me to further evaluate the drug.
Q. I know in 2001, which I know was before your time, CMS established a mailbox, an e-mail mailbox for feedback, at least on a particular federal upper limit list. I'm wondering if that in your tenure still existed.
A. Not that I know of.
Q. So to the extent that you got feedback by e-mail it would come to your e-mail address personally?
A. Correct.
Q. Would you talk to wholesalers in an effort to determine market availability?
A. No. I would only talk to the companies listed on in the compendia to determine availability or price, or try to determine.
Q. I think we're finally done with

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albuterol.
MS. OBEREMBT: Not all of us.
MR. BUEKER: I ask the court reporter to mark as Sexton Exhibit 12 for identification a one-page document that's Bates labeled HHD 175-2024.
(Exhibit Sexton 012 was marked for identification.)
BY MR. BUEKER:
Q. Please tell me when you've had a chance to take a look at Exhibit 12, Ms. Sexton.
A. (Reading.) Okay.
Q. Would you state for the record what Exhibit 12 is?
A. It's a pricing sheet generated from the federal upper limit software system.
Q. And there's handwriting on Exhibit 12. Whose handwriting is that?
A. That would be my handwriting.
Q. What drug does Exhibit 12 pertain to?
A. Isosorbide mononitrate.
Q. Can we refer to it as ISMN?

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